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## Drugs

### Early Communication about an Ongoing Safety Review of Omalizumab (marketed as Xolair)

7/16/2009

FDA is evaluating interim safety findings from an ongoing study of Xolair (omalizumab) that suggests an increased number of cardiovascular and cerebrovascular adverse events in a group of patients using Xolair compared to a group of patients not given the drug (control group).

Xolair is approved for use by adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who test positive for reactivity to a perennial airborne allergen, and whose symptoms are inadequately controlled with inhaled corticosteroids.

The ongoing study, titled *Evaluating the Clinical Effectiveness and Long-Term Safety in Patients with Moderate to Severe Asthma* (EXCELS), is an observational study of approximately 5000 Xolair treated patients and a control group of approximately 2500 non-Xolair treated patients. The primary objective of the EXCELS study is to assess the long-term safety profile of Xolair in patients followed for 5 years. Study patients are 12 years of age and older with moderate to severe persistent asthma and who have a positive skin test or blood test for an aeroallergen.

The interim data, submitted by the manufacturer of Xolair (Genentech), suggests a disproportionate increase in ischemic heart disease, arrhythmias, cardiomyopathy and cardiac failure, pulmonary hypertension, cerebrovascular disorders, and embolic, thrombotic and thrombophlebitic events in patients treated with Xolair compared to the control group of patients not given the drug.

FDA is not recommending any changes to the prescribing information for Xolair and is not advising patients to stop taking Xolair at this time. Until the evaluation of the EXCELS study is completed, healthcare providers and patients should be aware of the risks and benefits described in the prescribing information, as well as the new information from the ongoing EXCELS study that may suggest a risk of cardiovascular and cerebrovascular adverse events.

This early communication is in keeping with FDA's commitment to inform the public about ongoing safety reviews of drugs. FDA has not made any conclusions regarding these data. The Agency is working with Genentech to obtain further information and will continue to review the strengths and limitations of these interim results. For example, since EXCELS is an observational study, there could be differences in underlying risk factors for cardiovascular and cerebrovascular events between the two study groups. The Agency will communicate any new findings when its analysis of the interim safety data is complete. The EXCELS study is ongoing and final results are not expected until 2012.

The FDA urges both healthcare professionals and patients to report side effects from the use of omalizumab to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, using the contact information at the bottom of this page.

*This information reflects FDA's current analysis of available data concerning these drugs. Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue. Nor does it mean that FDA is advising health care professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available.*

### Related Information

- [Omaliuzumab \(marketed as Xolair\) Information](#)<sup>1</sup>

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